UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FERRING PHARMS. INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 15-802 (RC)
SYLVIA BURWELL, Secretary of Health and Human Services, *et al*.,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' RENEWED CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to this Court's March 15, 2016 Order, FDA hereby files a renewed cross-motion for summary judgment on the issue of whether FDA's new interpretation regarding new chemical entity ("NCE") exclusivity for fixed-dose combination products should apply retroactively. *See* Order (March 15, 2016). As discussed in the earlier round of briefing, FDA denied exclusivity to Ferring's product Prepopik, based on the agency's then extant interpretation that a fixed combination containing both a previously-approved and new active moiety is not eligible for 5-year NCE exclusivity. *See* Memo. in Supp. of Ds' Cross-Mot. for Summ. J. & Opp'n to Pl.'s Mot. for Summ. J. ("FDA SJ") at 9-12. Though Ferring and other petitioners were successful in convincing FDA that it should revise its interpretation as a matter of policy, FDA applied its interpretation only prospectively. Ferring now claims that fairness concerns demand retroactive application of the new interpretation.

The notions of fairness embedded in the retroactivity analysis, however, primarily concern adverse consequences to a party unaware that a new policy might be applied to it.

Ferring is asking this Court to turn the question of retroactivity on its head, arguing not that it would be unfair to apply a new policy retroactively but rather that it is unfair *not* to apply a new interpretation retroactively (*i.e.*, that it would be unfair to apply to Prepopik the interpretation that was in effect at the time Prepopik was approved). But this Court must also consider the fairness to other drug manufacturers who may have relied on application of the prior interpretation to Prepopik in their drug development plans. FDA's decision to apply the new interpretation prospectively only strikes the appropriate balance between the interests of the parties who may be affected by the interpretive change and the overarching intent behind the Hatch-Waxman Amendments to encourage innovation as well as competition.

The leading case on retroactivity in the D.C. Circuit is *Retail, Wholesale & Department Store Union v. NLRB*, 466 F.2d 380 (D.C. Cir. 1972). In that case, the court identified several factors that bear on a retroactivity analysis:

> Among the considerations that enter into a resolution of the problem [of retroactivity] are (1) whether the particular case is one of first impression, (2) whether the new rule represents an abrupt departure from well-established practice or merely attempts to fill a void in an unsettled area of law, (3) the extent to which the party against whom the new rule is applied relied on the former rule, (4) the degree of the burden which a retroactive order imposes on a party, and (5) the statutory interest in applying a new rule despite the reliance of a party on the old standard.

466 F.2d at 390 (court declined to retroactively apply a new standard that would have adversely impacted the employer who was in compliance with the old standard during the time in question). The *Retail Union* factors provide a framework for courts to balance any inequity in applying a new rule retroactively to parties who relied on the old rule, against the harm of not advancing the statutory purpose giving rise to the new rule in a given case. *Id.* The *Retail Union* analysis essentially "boil[s] down … to a question of concerns grounded in notions of equity and

fairness." *Cassell v. FCC*, 154 F.3d 478, 486 (D.C. Cir. 1998) (quoting *Clark-Cowlitz Joint Operating Agency v. FERC*, 826 F.2d 1074, 1081 (D.C. Cir. 1987) (en banc)).

The D.C. Circuit has varied its articulation of the *Retail Union* factors from case to case, but has concluded that, "[f]rom our experience in applying the various versions of the *Retail Union* test, there has emerged a basic distinction … between (1) new applications of law, clarifications, and additions, and (2) substitution of new law for old law that was reasonably clear." *Williams Nat. Gas Co. v. FERC*, 3 F.3d 1544, 1554 (1993) (internal quotation and citations omitted); *see also Aliceville Hydro Assocs. v. FERC*, 800 F.2d 1147, 1152 (D.C. Cir. 1986) (noting that the distinction stems from *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947)). When no clearly established policy exists, retroactive application of a newly-established policy is likely appropriate. *Id.* But when an established policy exists and the new policy is an abrupt departure from the previous policy, retroactive application "may give rise to questions of fairness" to those who relied on the preexisting policy. *See id.* "In a case in which there is a 'substitution of new law for old law that was reasonably clear,' a decision to deny retroactive effect is uncontroversial." *Verizon Tel. Cos. v. FCC*, 269 F.3d 1098, 1109 (D.C. Cir. 2001) (quoting *Epilepsy Found. v. NLRB*, 268 F.3d 1095, 1102 (D.C. Cir. 2001)).

This case falls squarely into the category of cases for which denying retroactive effect is "uncontroversial." *Id.* As in *Epilepsy Found. v. NLRB*, where the court found that the NLRB erred in retroactively applying a new policy because "[a]t the time when this case arose, the Board's policy . . . was absolutely clear," 268 F.3d at 1102, here too FDA's prior interpretation regarding the eligibility of fixed-combination products for 5-year NCE exclusivity was firmly established, consistently applied, and well-known to industry. *See, e.g.*, AR 208-11 (discussion in FDA's citizen petition response of the history of FDA's prior interpretation). The new

interpretation recognizes eligibility for 5-year NCE exclusivity of a drug substance that meets the definition of a new chemical entity (*i.e.*, does not contain any previously approved active moieties), regardless of whether the drug substance is first approved in a single-entity drug product or in a fixed-combination with another drug substance that does *not* meet the definition of new chemical entity. This new interpretation stands in stark contrast to FDA's prior interpretation. Moreover, it was only after FDA set forth its new interpretation and explained the reasons for adopting it in a draft guidance, and then finalized the guidance, that the new interpretation took effect. More significantly, all of this took place *after* Prepopik was approved.

At the time FDA answered the citizen petition regarding 5-year NCE exclusivity for fixed-combination products and decided to adopt a new interpretation of the relevant provisions, the fact of Prepopik's eligibility for 3-year rather than 5-year NCE exclusivity had been public knowledge for over a year. As explained previously, *see* FDA SJ at 25, while 3-year exclusivity does not block the submission of a 505(b)(2) application or ANDA relying on the exclusivity-protected drug, 5-year NCE exclusivity does. Had FDA applied its new interpretation retroactively to petitioners' products, any ANDA or 505(b)(2) application sponsor who may have commenced a development program relying on the fact that Prepopik and the other products at issue in the citizen petition were not eligible for 5-year NCE exclusivity would likely have been burdened by the change in the expected timeframe. Indeed, at least one generic manufacturer, Par Pharmaceuticals, has submitted an ANDA to FDA for a generic version of Prepopik, a fact that became public during patent litigation between Par and Ferring. *See* Par Pharmaceutical, Inc.'s Mot. to Intervene at 3, Dkt. No. 35. The "fairness" to Ferring of retroactive application of the new interpretation in this case is equalted, if not exceeded, by the unfairness to Par, which

presumably developed and sought approval for a generic product at least in part in reliance on FDA's prior interpretation.

Applying FDA's new interpretation only prospectively also does not frustrate the statutory purpose advanced by the new rule. As FDA noted in its citizen petition response, applying the new interpretation retroactively to Prepopik would not advance the Hatch-Waxman Amendments' goal of encouraging the development of novel new drugs because Prepopik has already been developed, and thus would not be incentivized by additional exclusivity. AR 215. The new interpretation will encourage the development of such drugs going forward.

Further counseling against applying FDA's new interpretation retroactively are the practical difficulties that would result. For example, would the new policy be applied retroactively only to Prepopik, to all three of the products discussed in the citizen petition, or to some as-yet-undetermined universe of fixed combination products previously approved by FDA? It is not clear how, or even if, FDA could reasonably apply the new policy retroactively to only certain fixed-combination products without running afoul of the Administrative Procedure Act. On the other hand, it would be unprecedented for this Court to order FDA to review all fixed-combination product approvals and retroactively apply the new interpretation to all approvals issued pursuant to the prior interpretation. Ferring has not shown, and cannot show, that such a drastic outcome is warranted here.

CONCLUSION

In sum, FDA's decision to apply the new interpretation prospectively accords with the relevant caselaw in this Circuit. Ferring has failed to demonstrate that the new policy must be applied retroactively and judgment should thus be entered in favor of the government.

Respectfully submitted,

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